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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,809	04/08/2004	Suketu P. Sanghvi	P0453.70116US01	9063
75	90 10/13/2006		EXAMINER	
Edward R. Gates Wolf, Greenfield & Sacks, P.C.			SPIVACK, PHYLLIS G	
600 Atlantic Avenue			ART UNIT	PAPER NUMBER
Boston, MA 0	2210		1614	
			DATE MAILED: 10/13/2006	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	10/821,809	SANGHVI ET AL.	
Office Action Summary	Examiner	Art Unit	
	Phyllis G. Spivack	1614	
The MAILING DATE of this communicati Period for Reply	on appears on the cover sheet v	vith the correspondence add	ress
A SHORTENED STATUTORY PERIOD FOR WHICHEVER IS LONGER, FROM THE MAILI - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communica - If NO period for reply is specified above, the maximum statutory - Failure to reply within the set or extended period for reply will, b Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	NG DATE OF THIS COMMUN CFR 1.136(a). In no event, however, may a tion. The period will apply and will expire SIX (6) MC To statute, cause the application to become A	ICATION. I reply be timely filed INTHS from the mailing date of this corr ABANDONED (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed or) .		•
, — · · · · · · · · · · · · · · · · · ·	This action is non-final.	•	
3) Since this application is in condition for a	-	tters, prosecution as to the r	merits is
closed in accordance with the practice u			
Disposition of Claims			
4)⊠ Claim(s) <u>1-112 and 114</u> is/are pending ir	the application.		
4a) Of the above claim(s) is/are w			
5) Claim(s) is/are allowed.		*	•
6) Claim(s) is/are rejected.			
7) Claim(s) is/are objected to.			· .
8)⊠ Claim(s) <u>1-112, 114</u> are subject to restrict	ction and/or election requireme	nt.	
Application Papers			
	·	•	
9) The specification is objected to by the Ex		. h., the Francisco	•
10) The drawing(s) filed on is/are: a)		-	
Applicant may not request that any objection			2.4.40441)
Replacement drawing sheet(s) including the	•	- , , ,	• •
11)☐ The oath or declaration is objected to by	the Examiner. Note the attache	ed Office Action or form P1C	<i>)</i> -152.
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for for	oreign priority under 35 U.S.C.	§ 119(a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:			
1. Certified copies of the priority docu		A . P . P . Ala	
2. Certified copies of the priority doct	•		11
3. Copies of the certified copies of th	•	n received in this National S	rage
application from the International E	, , , , , , , , , , , , , , , , , , , ,	A see a decad	
* See the attached detailed Office action for	a list of the certified copies no	t received.	
Attachment(s)			•
1) Notice of References Cited (PTO-892)		Summary (PTO-413)	
2) Notice of Draftsperson's Patent Drawing Review (PTO-9		(s)/Mail Date Informal Patent Application	
Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	6) Other:		
· · · · · · · · · · · · · · · · · · ·	<i>,</i> — —		

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Election

Claims 1-112 and 114 are generic to the following disclosed patentably distinct species: formulations or kits comprising a laxative or a stool softener in combination with a peripheral opioid antagonist for use in the treatment of constipation or a condition calling for treatment with a laxative, as disclosed in the present specification. The species are independent or distinct because they have different modes of operation or different effects.

Applicants are required under 35 U.S.C. 121 to elect single disclosed species for 1) a laxative; 2) a stool softener; 3) a peripheral opioid antagonist, even though this requirement is traversed. Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Where the Examiner has required restriction between product and process claims, and Applicants elect claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

<u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

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If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 2, 2006

Phyllis G. Spivack

PHYLLIS SPIVACK PRIMARY EXAMINER